UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

CODONICS, INC.,	
Plaintiff,	CASE NO. 1:08-CV-1885
vs.	OPINION & ORDER
DATCARD SYSTEMS, INC.,	[Resolving Doc. No. 62-1]
Defendant.	

JAMES S. GWIN, UNITED STATES DISTRICT JUDGE:

Defendant DatCard Systems, Inc. ("DatCard") moves this Court to dismiss Plaintiff Codonics, Inc.'s Complaint saying that this Court's adjudication of the claim would require it to "usurp [the Food and Drug Administration's] responsibility for interpreting and enforcing potentially ambiguous regulations." *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3rd Cir. 1990). [Doc. 62-1.] Codonics responds saying that this Court's adjudication of this case will not require it to interpret FDA regulations before the FDA has done so. [Doc. 71.]

In resolving this motion, this Court must decide (1) whether Congress intended the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*.; 52 Stat. 1040, and the Medical Device Amendments of 1976 ("MDA"), 90 Stat. 539, to pre-empt state law and federal Lanham Act claims, or (2) if adjudication of this motion would offend the primary jurisdiction of the FDA to interpret and apply its own regulations.

Because Defendant DatCard has not demonstrated that (1) Congress intended to pre-empt false advertising claims or (2) that this Court's adjudication of Codonics's false advertising claims will invade the primary jurisdiction of the FDA, this Court **DENIES** the motion to dismiss.

I. Background Facts and Procedure

Plaintiff Codonics, headquartered in the Northern District of Ohio, and Defendant DatCard, a California corporation, are "direct competitor[s] . . . in the medical imaging field." [Doc. 1-1 at 2-3.] Codonics sells both dry diagnostic medical imagers and CD/DVD disc publishers. [Doc. 1-1 at 2.] Codonics markets the CD/DVD disc publishers under the Virtua name. Codonics also provides film and media for use with its products. [Doc. 1-1 at 3.] Defendant DatCard sells a competing imager under the Smartline name and a competing CD/DVD medical image disc publisher under the PacsCube name. [Doc. 1-1 at 3-4.]

On January 18, 2008, DatCard filed a patent infringement action against Codonics in the United States District Court for the Central District of California saying that Codonics's Virtua CD/DVD disc publishers infringed DatCard's patent No. 7,302,164 (the "'164 patent"). [Doc. 14-2, Ex. A.] The '164 patent is titled "System and Method for Producing Medical Image Data Onto Portable Digital Recording Media." [Doc. 14-2, Ex. A at 3.] In response to the infringement claim, Codonics filed a request for reexamination of the '164 patent in the United States Patent and Trademark Office. [Doc. 48-18, Ex. 17 at 3-4.]

Around six and one half months after DatCard sued Codonics for patent infringement in California, "[o]n or about August 5, 2008," Codonics filed a Citizen Petition with the FDA because of its concerns with DatCard's "noncompliance with FDA regulations and . . . for patient safety." [Doc. 71 at 8-9.] In the Petition to the FDA, Codonics asserted that the PacsCube devices "failed to

possess their advertised standard of quality because Defendant's product manual failed to include a patient safety warning regarding the use of the produce in a healthcare environment," and that the SmartLine devices "are misbranded because they fail to provide certain required labeling information, including intended use and safety warnings." [Doc. 71 at 9.][1/]

At almost the same time as it filed its Citizen Petition with the FDA, on August 6, 2008, Codonics sued DatCard in this Court saying DatCard falsely advertised its PacsCube and Smartline products in violation of the Lanham Act, 28 U.S.C. § 1125(a)(1)(B). [Doc. 1-1.] Codonics additionally claimed that DatCard's conduct constituted (1) unfair competition under the Lanham Act, 15 U.S.C. § 1125(a)(1)(A), (2) deceptive trade under Ohio Revised Code §§ 4165.01-.04, and (3) unfair competition under Ohio common law. [Doc. 1-1 at 8-9.] Codonics complained that DatCard advertises its PacsCube and Smartline products "as being particularly suited for medical applications." [Doc. 1-1 at 3.] According to Codonics, however, DatCard's products are not suitable for use in the medical field because both lines of products include component parts that "can cause harm to patients in medical facilities." [Doc. 1-1 at 5.]

On January 30, 2009, the USPTO granted Codonics's request for reexamination. [Doc. 48-18, Ex. 17 at 3-4.] The district court in California has stayed that patent litigation pending the resolution of the patent reexamination. [Doc. 48-18, Ex. 17 at 3-4.]

On May 4, 2009, Defendant DatCard moved this Court to dismiss Plaintiff Codonics's claims saying that Codonics's Citizen Petition with the FDA supports a finding that adjudication of these claims would improperly usurp the role of the FDA in interpreting and administering the regulations

[1/] Codonics also asserted that the two lines of products were mis-classified under the Medical Device Amendments to the Food, Drug, and Cosmetic Act. [Doc. 71 at 9, n.1.]

on medical devices.

II. Pre-emption

"[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth v. Levin*, 129 S. Ct. 1187, 1194-95 (2009). (citations and internal quotations omitted). Because "[t]he pre-emption doctrine . . . has its roots in the Supremacy Clause," *Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152 (1982) (citations omitted), the relationship between the federal government and the states is the animating force behind Supreme Court's recent jurisprudence on pre-emption. *Wyeth*, 129 S. Ct. at 1194.

In its motion to dismiss, Defendant DatCard does not distinguish between Plaintiff Codonics's state tort claims and federal Lanham Act claims. This distinction, however, is important. Out of concern for disturbing the balance between the federal government and the states, in state "preemption cases . . . [courts] 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Id.* (quoting *Lohr*, 518 U.S. at 485). But when analyzing pre-emption of a federal cause of action, "no presumption against pre-emption obtains . . . ." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001) (discussing preemption claims that do not involve federalism concerns). Because of this difference, this Court will analyze pre-emption separately.

II.A. Pre-emption of State Law Claims

Around two months before DatCard filed its motion to dismiss, the Supreme Court issued an opinion discussing many of the same pre-emption issues that the parties are litigating in this case. *See Wyeth v. Levine*, 129 S. Ct. 1187 (2009). In *Wyeth* the defendant drug-manufacturer had argued that the plaintiff's state law tort claims were "pre-empted because they interfere with Congress's

purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives." *Id.* at 1199. But the Supreme Court rejected this argument after finding Congress had not intended to pre-empt state common law tort suits. *Id.* at 1200 ("[Congress's] silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.").

Here, Defendant DatCard proffers an almost identical argument: DatCard says that Congress intended to pre-empt Condonics's claims (both state and federal) by vesting the FDA with exclusive authority to make decisions on the suitability of a medical device for use in the medical field. In light of the *Wyeth* case and the high burden that a proponent of pre-emption faces, here, DatCard has not shown that Congress intended to pre-empt state law tort claims when it gave the FDA authority to implement the FDCA and MDA. Accordingly, this Court denies DatCard's motion to dismiss on the state law claims.[2/]

II.B. Pre-emption of Federal Claims

Wyeth does not control the pre-emption of federal law claims. As noted above, when pre-emption does not involve the relationship between the federal government and the states,"no presumption against pre-emption obtains . . . ." *Buckman*, 531 U.S. at 348 (discussing preemption claims that do not involve federalism concerns).

[2/] This holding is narrow and reflects the limited argument that DatCard made. Pre-emption analysis of state law claims is different for a medical device (the subject here) than for a prescription drug (the subject of *Wyeth*). In 21 U.S.C. § 360k, Congress enacted an "express pre-emption provision for medical devices . . . [but] has not enacted such a provision for prescription drugs." *Wyeth*, 129 S.Ct. at 1200 (citations omitted); 21 U.S.C. § 360k. DatCard, however, has made no argument that 21 U.S.C. § 360k pre-empts Codonics's state law claims. Accordingly, this Court will not reach this issue. *Cf. Buckman*, 531 U.S. at 348 n.2 ("In light of th[e] conclusion [that the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law], we express no view on whether these claims are subject to express pre-emption under 21 U.S.C. § 360k.").

Plaintiff Codonics alleges violations of the Lanham Act. The FDA, however, through the FDCA and the MDA, is primarily responsible for the regulation of medical devices. *Buckman*, 531 U.S. at 343. The FDCA and the MDA, however, do not allow a private right of action. 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 349 n.4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions."); *In re Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 781 (3rd Cir. 1999) ("It is well settled . . . that the FDCA creates no private right of action.").

DatCard says that allowing Codonics to bring its claim for false advertising under the Lanham Act would allow Codonics to use the Lanham Act to "create indirectly" a private cause of action to enforce the FDCA and the MDA when neither of those acts allow a private right of action. *Sandoz*, 902 F.2d at 231.

Even without the presumption against pre-emption, however, DatCard has not shown that Congress intended the FDCA and the MDA to pre-empt Lanham Act claims for false advertising. The FDCA "as a whole was designed primarily to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 969 (1948). "The MDA comprehensively regulates medical devices." *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090, 1095 (6th Cir. 1997). Where the MDA and the FDCA are intended to protect the safety of consumers, the Lanham Act is "primarily intended to protect commercial interests." *Sandoz*, 902 F.2d at 231 (citations omitted). "A competitor in a Lanham Act suit does not act as a vicarious avenger of the public's right to be protected against false advertising." *Id.* (citations and internal quotations omitted).

The two statutes protect different interests and DatCard has not demonstrated that Congress intended to the FDCA to pre-empt Lanham Act claims whenever a case involves a medical device.

III. Usurping FDA Authority

DatCard also says that, if this Court were to adjudicate Codonics's claims, it would "usurp [the Food and Drug Administration's] responsibility for interpreting and enforcing potentially ambiguous regulations," *Sandoz*, 902 F.2d at 231. Because the FDCA does not create a private right of action and the FDA is primarily responsible for interpreting its own regulations, courts have recognized the potential problem of allowing a Lanham Act claim the directly turns on the interpretation of FDA regulations.

Several courts have noted the difficulty of defining the relationship between the FDCA and the Lanham Act. *See Solvay Pharmaceuticals, Inc. v. Ethex Corp*, No. Civ. 03-2836 JRTFLN, 2004 WL 742033, *3 (D. Minn. Mar. 30, 2004) ("Courts have recognized the potential conflict between the two Acts and have struggled to define the proper scope of each law."); *Sirius Laboratories, Inc. v. Rising Pharmaceuticals, Inc.*, No. 03 C 6965, 2004 WL 51240 (N.D. Ill. Jan. 7, 2004) ("Unfortunately, [t]here is no single, bright-line test to distinguish sustainable from non-sustainable claims.") (citations and internal quotations omitted).

Most courts, though, have allowed Lanham Act claims for false advertising of food or drugs to proceed, despite applicability of FDA regulations to the allegedly false advertising, when (1) the plaintiff can prove the falsity of the advertising without the use of FDA regulations, such as by reference to a market definition of the term;[3/] or (2) the plaintiff can prove the falsity of the

[3/] *Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc.*, 720 F. Supp. 714, 716 (N.D. Ill. 1989) ("[Plaintiff] would simply need to provide other evidence establishing the proper market definition of 'orange juice from concentrate.'")

advertising through reference to an unambiguous FDA definition.[4/]

In order to prove its Lanham Act claims, Codonics must show that DatCard "use[d] in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact." 15 U.S.C. § 1125(a)(1).[5/] Codonics complains that DatCard "touts its PacsCube Products and SmartLine Products as being particularly suited for medical applications." [Doc. 1-1 at 3.] According to Codonics, however, these products, however, "are not suitable for use in medical applications" because they contain component parts (non-medical grade power sources) that "are known to emit current leakage which can cause harm to patients in medical facilities." [Doc. 1-1 at 5.]

The precise scope, however, of Codonics's claims has not been completely defined at this stage in the litigation. Although the Complaint focuses on the potential for harm to patients in medical facilities, Codonics is not limited to this safety concern in its claims that DatCard's statements on suitability were false. Additionally, DatCard has not shown, other than conclusory statements, why this Court will be required to usurp the authority of the FDA and, if so, what ambiguous regulations this Court will be required to interpret. [*See* Doc. 62-1 at 6 (saying that the FDA has exclusive authority over the advertising of DatCard's products because, in its Citizen's Petition, "Codonics maintains . . . that the advertising and marketing of [DatCard's] products are

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[4/] *See Sirius*, 2004 WL 51240 at *3 ("[Plaintiff] is simply relying on the USP definition of 1% anthralin cream to establish the standard which [defendant] failed to meet. This standard is not ambiguous, nor is it subject to interpretation of the exercise of some discretion.").

[5/] Codonics Lanham Act claims are both premised on this showing of a false or misleading description of fact. [Doc. 1-1at 7-8.]

regulated by the FDA under 21 U.S.C. § 351(c)).]

Defendant DatCard has not shown that this Court's adjudication of Codonics's claims would necessarily usurp the authority of the FDA. This Court's ruling is based on DatCard's failure to demonstrate that it is entitled to dismissal. This ruling should not foreclose a better developed argument at the summary judgment stage.

V. Conclusion

For the reasons stated above, this Court **DENIES** Defendant DatCard's motion to dismiss or transfer.

IT IS SO ORDERED.

Dated: July 31, 2009

s/ *James S. Gwin*
JAMES S. GWIN
UNITED STATES DISTRICT JUDGE